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OCT 5 " 2007

510(k) SUMMARY

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K071340

A. Introduction:

According to the requirements of 21 CFR 807.92 the following information provides sufficent detail to understand the basis for a determination of substantial equivalence.

B. Submitter's information

Name:	Thermo Fisher Scientific Oy
Address:	Ratastie 2 P.O. Box 100 FIN-01621 Vantaa Finland
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Contact person:	Päivi Sormunen, Vice President of QRC
Date of Preparation:	May 10th, 2007

C. Device name

Proprietary name:	Carbon Dioxide (CO2)
Common name:	Carbon Dioxide (CO2)
Classification:	Clinical Chemistry
Class:	II
Product Code:	KHS
Proprietary name:	sCal, code 981831
Common Name:	Calibrator, Multi-Analyte Mixture
Classification:	Clinical Chemistry
Class:	II
Product Code:	JIX
Proprietary name:	Nortrol, code 981043
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY
Proprietary name:	Abtrol, code 981044
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY

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D. Intended Use

Carbon Dioxide (CO2)
For in vitro diagnostic use in the quantitative determionation of the bicarbonate (CO_2) concentration in human serum or plasma (Li-heparin) on T60 instrument

sCal
For in vitro diagnostic use on T60 analyzer. sCal is used as a multicalibrator for quantitative measurements using methods defined by Thermo Fisher Scientific Oy.

Nortrol
For in vitro diagnostic use for quantitative testing on T60 analyzer. Nortrol is a control serum to monitor trueness and precision of the analytes listed in the separate Nortrol value sheet. The given values are valid for T60 Clinical Chemistry Analyzers using methods defined by Thermo Fisher Scientific Oy.

Abtrol
For in vitro diagnostic use for quantitative testing on T60 analyzer. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Analyzers using methods defined by Thermo Fisher Scientific Oy.

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E. Indications for use

Carbon Dioxide (CO2) Reagent is intended for the quantitative determination of total carbon dioxide in human serum.
Bicarbonate measurements, in conjunction with tests such as glucose, urea, sodium, potassium and chloride, are used in the assessment of disturbances of acid base balance resulting from metabolic or respiratory causes

For sCal Calibrator, Nortrol, Abtrol Controls see intended use

F. Substantial Equivalence

Roche Diagnostics Corporation, model Hitachi 911
Roche Diagnostics Corporation item:
CO2-L (Bicarbonate Liquid) (K032377).

G. Substantial equivalence -similarities

The Carbon Dioxide (CO2) is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Roche Diagnostics Corporation CO2-L (Bicarbonate Liquid).

The following table compares the Carbon Dioxide (CO2) with the predicate device.
Table 1

Attribute	**New device #1**	**Predicate device #1**
Intended Use	For in vitro diagnostic use in the quantitative determionation of the bicarbonate (CO_2) concentration in human serum or plasma (Li-heparin) on T60 instrument.	In vitro test for the quantitative determination of bicarbonate in human serum and plasma on Roche automated clinical chemistry analyzers.
Indication for Use	Carbon Dioxide (CO2) Reagent is intended for the quantitative determination of total carbon dioxide in human serum. Bicarbonate measurements, in conjunction with tests such as glucose, urea, sodium, potassium and chloride, are used in the assessment of disturbances of acid base balance resulting from metabolic or respiratory causes.	See intended use.
Assay Protocol	Enzymatic rate	Enzymatic rate
Traceability/Standardization	Traceable to RCPA AQAP Cycle 71	Traceable to NIST
Sample Type	Serum, plasma (Li-heparin)	Serum, plasma (Li-heparin)
Reagent Storage	Reagents in unopened vials are stable at 2…8 °C until the expiry date printed on the label.	Shelf life at 2 to 8 °C until the expiration date on cassette.
Expected Values	Adult: 22 – 29 mmol/L	22 – 29 mmol/L
Instrument	T60 and DPC T60i, DPC T60i Kusti	Hitachi 911
Measuring Range	5 – 40 mmol/L	1.5 – 50 mmol/L

Attribute	New device #1	Predicate device #1
Precision	**Within run** Level 15.7 mmol/L SD= 0.3 CV(%)= 1.9 Level 25.2 mmol/L SD=0.4 CV(%)= 1.6 Level 34.3 mmol/L SD= 0.4 CV(%)= 1.3 **Between run** Level 15.7 mmol/L SD= 0.8 CV(%)= 5.3 Level 25.2 mmol/L SD= 1.0 CV(%)= 3.9 Level 34.3 mmol/L SD= 1.5 CV(%)= 4.5 **Total** Level 15.7 mmol/L SD= 1.0 CV(%)= 6.1 Level 25.2 mmol/L SD= 1.2 CV(%)= 4.9 Level 34.3 mmol/L SD= 1.6 CV(%)= 4.7	**Within run** Level 20.5 mmol/L SD = 0.18 CV(%)= 0.9 Level 34.4 mmol/L SD = 0.19 CV(%)= 0.6 **Between run** Level 17.8 mmol/L SD = 0.4 CV(%)= 2.5 Level 29.8 mmol/L SD = 0.5 CV(%)= 1.8
Method Comparison	**Serum and plasma (Li-heparin) :** y = 0.978x + 1.23 R = 0.983 Range 9.1 to 49.5 mmol/L N = 100 **Serum:** y = 0.972x + 1.40 R = 0.9835 Range 9.1 to 49.5 mmol/L N = 71 **Plasma (Li-heparin):** y = 1.046x - 0.24 R = 0.9816 Range 11.4 to 45.2 mmol/L N = 29	Y = 1.01 x – 0.89 R = 0.998 Range 0.67 to 46 mmol/L N = 59

Attribute	New device #1	Predicate device #1
Limitations	**Lipemia**: No interference found up to 2000 mg/dL (20 g/l) of Intralipid. **Hemoglobin:** No interference found up to 1000 mg/dL (10 g/l) of hemoglobin. **Hemolysate:** No interference found up to 400 mg/dl (4 g/l) of hemoglobin in hemolysate **Bilirubin, conjugated:** No interference found up to 60 mg/dL (1000 µmol/l) of conjugated bilirubin. **Bilirubin, unconjugated:** No interference found up to 60 mg/dL (1000 µmol/l) of unconjugated bilirubin.	**Lipemia (Intralipid):** No significant interference up to an L index of 2000. **Hemolysate:** No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 1000 mg/dL or 621 µmol/L). **Bilirubin, conjugated / unconjugated:** No significant interference up to an I index of 60 for conjugated bilirubin and an I index of 50 for unconjugated bilirubin (approximate conjugated bilirubin concentration: 60 mg/dL or 1026 µmol/L; approximate unconjugated bilirubin concentration: 50 mg/dL or 855 µmol/L).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Thermo Fisher Scientific
c/o Ms. Paivi Sormunen
Vice President of Industrial Solutions
and QRC
Clinical Diagnostics Finland
Ratastie 2, P.O. Box 100
FIN-01621 Vantaa, Finland

OCT 5 2007

Re: k071340
Trade Name: Carbon Dioxide (CO2), sCAL, Nortrol, Abtrol
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Code: KHS, JIX, JJY
Dated: September 4, 2007
Received: September 6, 2007

Dear Mr. Sormunen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071340

Device Names: **Carbon Dioxide (CO2)**
sCal
Nortrol
Abtrol

Indications for Use:

Carbon Dioxide (CO_2)

Carbon Dioxide (CO_2) reagent is intended for the quantitative determination of total carbon dioxide in human serum and plasma (Li-heparin) on T60 analyzer.
Bicarbonate measurements, in conjunction with tests such as glucose, urea, sodium, portassium and chloride, are used in the assessment of disturbances of acid base balance resulting from metabolic or respiratory causes

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Prescription Use X (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071340